

4. 510(k) Summary

K122156

page 1/3

Contact:

Howard Schraye
c/o Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533
Telephone: 609-924-9510
Fax: 914-231-7884
hs.ss@verizon.net

JAN 28 2013

Date Prepared:

December 21, 2012

Manufacturer:

Orthocon®, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533

Device Trade Name:

Orthocon Absorbable Hemostatic Bone Putty

Common Name:

Bone wax

Classification:

Unclassified

Product Code:

MTJ

Predicate Devices

Ceremed, Inc.
Ostene AOC Bone Wax
K041363 and others

Synthes (USA)
Synthes Hemostatic Bone Putty
K113079 and others

Ethicon, Inc.
Ethicon Bone Wax
pre-amendment

Device Description:

Orthocon Absorbable Hemostatic Bone Putty is a sterile, soft, moldable, biocompatible, water soluble and absorbable material of putty-like consistency intended for use in the control of bleeding from bone surfaces by acting as a mechanical barrier or tamponade. The material is a mixture of alkylene oxide polymer based materials and carboxymethylcellulose sodium salt. The material is virtually odorless, off-white in color and can be spread easily with minimal adhesion to surgical gloves. The bone putty requires no kneading prior to application.

Intended Use (Indications):

Orthocon Absorbable Hemostatic Bone Putty is indicated for use as an absorbable implant material for the control of bleeding from bone surfaces.

Substantial Equivalence and Predicate Devices:

The submission supports the position that Orthocon Absorbable Hemostatic Bone Putty is substantially equivalent to a number of previously cleared bone wax devices including Ceremed - Ostene AOC Bone Wax (K041363 and others), Synthes (USA) - Synthes Hemostatic Bone Putty (K113079 and others); and Ethicon Bone Wax (pre-amendment).

The technological characteristics (i.e., resorbable, water-soluble putty formulations) are equivalent to the characteristics of the Ceremed and Synthes predicates. Both of these predicates and Orthocon Absorbable Hemostatic Bone Putty incorporate alkylene oxide polymers in the formulation. The Synthes predicate also shares a carboxymethylcellulose component. Each of these devices (and the predicate Ethicon bone wax) accomplish their clinical purpose through mechanical tamponade.

Bench, biocompatibility and animal testing performed on the Orthocon Absorbable Hemostatic Bone Putty demonstrate the device is substantially equivalent to predicate devices in intended use and performance. This testing included the following:

Bench Testing was conducted to verify the device's handling properties, to characterize the device's performance over a range of temperatures and to evaluate the device's dissolution and swelling properties. The following bench studies were completed: smearability, stickiness, stiffness, temperature sensitivity, and dissolution and swelling.

Biocompatibility Testing was conducted to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, sterilized device in accordance with GLP requirements: cytotoxicity, irritation, sensitization, acute systemic toxicity, genotoxicity, implantation/subacute toxicity, hemolysis, and pyrogenicity.

In vivo Testing included comparative animal studies to demonstrate intraoperative hemostasis, resistance to irrigation, ability to remove the device, and to characterize its absorption time.

All of the testing demonstrated that Orthocon Absorbable Hemostatic Bone Putty met its design criteria and, as relevant, performed in a manner equivalent to the predicate devices.

Conclusion:

Orthocon, Inc. believes that it's the information provided establishes that similar legally-marketed devices have been used for the same clinical indications as Orthocon Absorbable Hemostatic Bone Putty and that the device is substantially equivalent to previously cleared bone wax devices. The device has been tested in accordance with all relevant standards and guidelines.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Orthocon, Incorporated
% Mr. Howard Schraye
1 Bridge Street, Suite 121
Irvington, New York 10533

January 28, 2013

Re: K122156

Trade/Device Name: Orthocon Absorbable Hemostatic Bone Putty

Regulatory Class: Unclassified

Product Code: MTJ

Dated: December 28, 2012

Received: December 31, 2012

Dear Dr. Schraye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K122156

Device Name: Orthocon Absorbable Hemostatic Bone Putty

Orthocon® Absorbable Hemostatic Bone Putty is indicated for use as an absorbable implant material in the control of bleeding from bone surfaces.

Prescription Use ✓ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122156